REMARKS

Claims 1, 2, 3, 5, 7, and 9 are hereby amended. claim 4 is hereby canceled without prejudice or disclaimer, and new claims 33-35 are hereby presented for Examiner's consideration. Claims 1-3, 5-10 and 33-35 remain in the application. The foregoing separate sheets marked as "Listing of Claims" show all the claims in the application, with an indication of the current status of each.

Applicant reserves the right to pursue the subject matter of canceled claims, or of subject matter canceled from the claims, or of any unclaimed subject matter, in future continuation or divisional applications.

Drawings

Applicant acknowledges that objections to the claims are being held in abeyance by Examiner.

Specification

Applicant further acknowledges that the disclosure could be objected to because is does not use reference numbers when referring to the parts of the drawings. It is Applicant's understanding that this objection is also being held in abeyance.

In addition, Examiner's reference to the use of third party trademarks is noted.

Claim Rejections: 35 USC § 112, second paragraph

Claim 4 stands rejected under 35 USC § 112, second paragraph, as indefinite. According to the Examiner, the claims contains improper Markush grouping.

Applicant has hereby canceled claim 4, making moot this rejection. A portion of the subject matter of canceled claim 4 is now recited in new claims 33-35. Applicant thus submits that new claims 33-35 do not add new matter to the application, being derived entirely from canceled claim 4. Applicant therefore respectfully requests entry, examination and allowance of these new claims.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claim Rejections: 35 USC § 101

Claims 1-10 stand rejected under 35 USC § 101, as ostensibly directed to unpatentable subject matter. According to Examiner, the claims are held to an abstract

idea. Examiner opines that the claims recite an idea, since no recitation of a machine or transformation is expressed or inherent. This rejection is traversed.

Claim 1 recites a method which comprises a step of intentionally varying an amount of at least one of the one or more inactive ingredients to intentionally generate a product tag of the pharmaceutical product. Claim 3 recites a step of intentionally varying an amount of at least one of the one or more inactive ingredients among different batches of the pharmaceutical product. In both methods, the step of intentionally varying the composition must, by definition, result in a change (variation) in the product's composition, and hence a "transformation". Thus, contrary to Examiner's assertion, claims 1 and 3 are both directed to patentable subject matter. All other claims in the application depend from claim 1 and are thus also directed to patentable subject matter.

In addition, claim 1 is hereby amended to recite "wherein the product tag varies from a reference product tag of the pharmaceutical product" thereby further emphasizing the transformation that occurs when the method is practiced. Support for this language is found in the application as filed, for example, in paragraphs [0022], [0094] and [0095] of the published application. Thus, this amendment does not add new matter to the application.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claim Rejections: 35 USC § 103(a)

Julia and Rzasa

Claims 1-2 stand rejected under 35 USC § 103(a) as obvious over Julia (US patent 6,907,351) in view of Rzasa (US 6,771,369). This rejection is traversed.

The rejection is based on a combination of Julia and Rzasa. The teachings of Julia are first discussed in detail in order to clearly explain what a hypothetical "composition" of the two references would involve.

In paragraph 2, page 6 of the Office Action, the Examiner states that "Julia discloses: intentionally varying an amount (Abstract "predicting content levels of components in materials")…". In so doing, it appears that Examiner is equating the step of "intentionally varying an amount of at least one of the one or more

components in a product" (from claim 1 of the present invention) with "predicting content level of components in materials" (the references phrase from the abstract of Julia). This purported equivalence is incorrect. In order to establish such an equivalence, one would have to erroneously equate the well-established, conventional meanings to the verbs "vary" and "predict". Applicant notes that in fact, these two words have very different meanings (see attached definitions from the Merriam Webster online dictionary). To "vary" is to change, make differences between, take on successive values, etc. whereas to "predict" is to declare or indicate in advance. "Predicting content level of components in materials" bears no resemblance to "intentionally varying an amount of at least one of the one or more components in a product", a step that is required in the method of the present claims, and which is not taught or suggested by Julia. Julia has no reason to vary ingredients of a material, and in fact, this would not be possible to do when practicing the method of Julia. A practitioner of Julia does not have "the material" and is not manufacturing anything. The customer has "the material" and sends only an NIRS of the same to a practitioner of the Julia method for comparative analysis. In contrast, a practitioner of the present invention is a manufacturer and/or formulator of the material, and must select at least one component to vary, and see that the product is manufactured with the selected variation(s). The two methods are fundamentally unrelated, and have no steps in common.

These differences are not surprisingly, since the technology of Julia solves an entirely different problem than that which is solved by the present invention. The problem addressed by Julia is that the compositions of materials (e.g. animal feeds, pharmaceuticals, etc.) can vary widely. This is true for materials obtained from different sources, from a single source at different times, or from a single source but from different batches. Thus, a customer who is using a purchased material is at the mercy of information provided by the source with respect to what is actually in the material. The consequences can be grave, especially when e.g. foodstuffs and body-treating compositions are at issue. Julia provides an analytical service that solves this problem.

The example used by Julia is animal feed. The requirements for good animal nutrition are known and adequate levels of certain nutrients must be maintained or proper health and development can be impaired. Yet how is a purchaser to ascertain the actual level or amount of e.g. a particular vitamin or mineral in material obtained from a source? Most prior art methods, e.g. chemical analysis, are expensive and time consuming. The method of Julia takes advantage of the unique near infrared reflectance spectra (NIRS) emitted by different materials, and the ease and rapidity of obtaining and analyzing such spectra, so that a customer can know with certainty, how much of a component is present in a material prior to its use (which could be resale, or use as an ingredient in another product, etc.). Julia uses the word "predict" only in the sense that a customer can know e.g. after purchasing (or obtaining a sample of) a material, but *before using* the material, the amount of a component of interest that is present in the material.

According to Julia, a request for confirmation of the amount of a component in a material is submitted electronically by a customer to the service. Significantly, the request must include an NIRS of the material in question (see column 3, lines 59-60 "wherein the request includes a near infrared reflectance spectrum of the material"; column 4, lines 46-47: "Customer 110 may create the near infrared spectra using any appropriate NIRS equipment."; and claim 1). In other words, the method of Julia requires the customer who uses the analytical service to provide an NIRS of the material to the service. The service maintains a database of known NIR spectra of the component e.g. in a variety of materials, and can correlate the customer spectrum to standards (calibrating and correcting as necessary), in order to provide the customer with a determination (or, as used by Julia, a "prediction") of the amount of the component that is present. The amount is "predicted" in the sense that the customer who uses this analytical service can know the amount of a component "in advance" of doing something with the material e.g. in advance of selling or using the material to manufacture goods.

In sharp contrast, the method of the present invention is not in any sense an analytical service. Rather, it is a method that would be used by a manufacturer to produce a product with a covert, intrinsic "label" or "tag" (paragraphs [0015] -

[0016]), the purpose of which is to allow authentication of manufactured goods, or, conversely, the detection of counterfeit goods (paragraph [0022]). The method may also be used to fingerprint products as to the manufacturer and/or production batch, or for other reasons (see paragraph [0027]). In direct contrast to Julia, the composition of the goods and/or the amount of a component in a material with respect to quality or efficacy is not the issue. The present invention makes the assumption that the goods or materials at issue are produced using whatever components are desired or necessary. The method of the present invention is practiced when a desired composition of a material, with respect to quality or the functioning of the material, has already been developed. The purpose of the invention is to then "tag" or label the material with a covert, intrinsic label. In the practice of the method, at least one component of the material is selected (e.g. one that is inactive or non-essential), and its amount of that component is varied intentionally for the sole purpose of creating a distinctive NIR spectrum of the material (paragraph [0078]). This has nothing to do with the quality of the product or how well it performs when used, or the amount of any other component, but only with tracking authentic product or product batches (or, conversely, detecting non-authentic product.) For example, an inert ingredient (e.g. component "X") may be selected and its amount varied (e.g. ±10 %) above that which is usually present in the material. The NIRS of material with a ±10 % variation in X differs from the NIRS of material having the usual amount of X. A counterfeiter, when attempting to illicitly manufacture the same material, would have no way to know that the amount of X had been changed (varied) ±10 %, and hence would have no reason to copy the altered composition. NIR spectra of the counterfeit goods would thus appear "normal" with respect to X, and authentic goods would have a spectrum in which NIR spectra showed a ±10 % change in X, when compared to the unlabeled material (e.g. counterfeit material, or material produced by a different manufacturer, or from a different batch, location, etc., (paragraph [0016]).

According to the present invention, the component to vary is selected with care so that its variation does not alter the properties of the material. For example, in pharmaceuticals, it is not likely to be the main active ingredient. Further, the variation in amount is within prescribed limits, if need be, so as not to compromise the quality

or integrity of the product, or to violate established standards (paragraphs [0086] - [0088]). Further, the amount of more than one component may be varied if desired (paragraphs [0031]-[0032]), to generate a more complex and difficult to anticipate (and copy) NIRS. In addition, the component that is varied, and/or the amount of variation, may be changed from time to time, or from batch to batch, etc., in order to further foil attempts to reproduce the composition (see paragraphs [0028], [0083], and others).

Examiner has cited Rzasa only as teaching that the term "signature" is a term of art for identifying a pharmaceutical by the quantity of an ingredient. Firstly, claim 1 as amended does not recite "signature" but instead "tag", a recitation that is supported, for example, in paragraphs [0022], [0073] and [0074] of the application as published. Further, it is Applicant's position that the teachings of Rzasa do not in any way supply or mitigate the defects of Julia. Rzasa also does not teach or suggest intentionally varying an amount of an ingredient in a composition in order to "tag" the composition, or batches of a composition.

With respect to claim 2, Examiner merely looks to Julia for a further teaching of the use of NIR spectra, which teaching does not in any way cure or mitigate the defects of Julia as a whole, with respect to the rejection of claim 2.

In summary, Julia does not render the method of the present invention obvious when combined with Rzasa. Julia teaches a method that has no steps in common with the method of the present invention, and which is designed to solve a completely different problem, and to be practiced by a different entity than is the method of the present invention. Further, there is no way to modify the method of Julia using the teachings of Rzasa and arrive at the present method. As cited by the Examiner, Rzasa provides only teachings of the meaning of a product "signature", a term which is not recited in the present claims, and which does not, in any case, address the meaning or mechanics of the practice of the present method. The present method deals with formulating compositions of materials, whereas Julia deals only with comparing an NIRS, provided by a customer, with spectra in a database in order to determine the amount of a compound of interest in the material from which the customer's NIRS

was derived. Therefore, no combination of Julia and Rzasa renders obvious the subject matter of claims 1 and 2.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Julia in view of the background of Julia

Claim 3 stands rejected under 35 USC § 103(a) as obvious over Julia (as above) in view of the background of Julia. This rejection is traversed.

The teachings of Julia are described in detail in the preceding section. Briefly, Julia deals only with comparing an NIRS, provided by a customer, with spectra in a database in order to determine the amount of a compound of interest in the material from which the customer's NIRS was derived. Julia neither discloses nor suggests a step of intentionally varying an amount of a component of a composition (or of a batch formulation of a composition) in order to tag or label the composition, e.g. to distinguish it from other batches of the same composition, or from counterfeit compositions, etc. In fact, Julia does not teach varying anything, but only predicting/detecting possible variations. In contrast, a step of intentionally varying is required in the method of claim 3.

Examiner appears to cite the background of Julia only as teaching batch production of products. Clearly, this minimal teaching does not cure the deficiencies to Julia as a whole with respect to the subject matter of claim 3. Thus, no combination of any teachings within Julia, or any other reference, renders that subject matter of claim 3 obvious.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Julia in view of US FDA Guidance

Claims 4-10 stand rejected under 35 USC § 103(a) as obvious over Julia (as above) in view of the US FDA guidelines for scale-up and post-approval for products. This rejection is traversed.

Claim 4 is hereby canceled, thereby making moot this portion of the rejection.

With respect to the rejection of claims 5-10, the defects of Julia as a prior art reference are discussed in detail above. The bottom line is that Julia neither teaches

nor suggests intentionally varying anything, but is merely an analytical method for detecting fluctuations in product formulation. Since claims 5-10 are dependent on claim 1, and claim 1 is clearly drawn to patentable subject matter, claims 4-10 are also patentable.

Further, the citation of FDA guidelines fails to supply or even address the teachings that are missing from Julia. The Examiner states that varying the amounts of inactive ingredients is well known, as evidenced by the FDA guidelines. However, these guidelines do NOT teach purposefully or intentionally varying these amounts in order to create a covert tag or label of a product, and that is what the claims recite and require. Rather, the guidelines merely provide e.g. conservative recommended limits of such ingredients. The method of the present invention does not rely on particular types or levels of ingredients in order to be novel, but rather on the step of intentionally varying an amount of an ingredient in a composition with the particular goal of tagging (e.g. labeling or distinguishing) the composition, e.g. from other batches of the composition, either bona fide batches made by an authorized manufacturer or illicit batches made by a counterfeiter. A reference to particular types of inactive ingredients or particular levels as taught in the FDA guidelines (or elsewhere) do not cure or mitigate the deficiencies of Julia, and hence do not, in combination with Julia or any other reference, render the present invention , as claimed in claims 5-10 and new claims 33-35, obvious.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of this rejection.

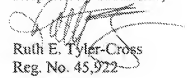
Concluding Remarks

In view of the foregoing, it is requested that the application be reconsidered, that claims 1, 2, 6, 7, 8, 12, and 28-34 be allowed, and that the application be passed to issue.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at 703-787-9400 (fax: 703-787-7557; email: ruth@wcc-ip.com) to discuss any other changes deemed necessary in a telephonic or personal interview.

If an extension of time is required for this response to be considered as being timely filed, a conditional petition is hereby made for such extension of time. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,



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pre·dict verb \pri-'dikt\

Like

Definition of PREDICT

transitive verb

: to declare or indicate in advance; *especially* : foretell on the basis of observation, experience, or scientific reason

intransitive verb

: to make a prediction

- **pre·dict·abil·i·ty** *noun*
- **pre·dict·able** *adjective*
- **pre·dic·tive** *adjective*
- **pre·dic·tive·ly** *adverb*
- **pre·dic·tor** *noun*

See predict defined for English-language learners »
See predict defined for kids »

Examples of PREDICT

All the local forecasters are *predicting* rain for this afternoon.

She claims that she can *predict* future events.

It's hard to *predict* how the election will turn out.

Many people *predicted* that the store would fail, but it has done very well.

Sales are *predicted* to be the same as last year.

Origin of PREDICT

Latin *praedictus*, past participle of *praedicere*, from *prae-* pre- + *dicere* to say — more at DICTION

First Known Use: 1609

Related to PREDICT

Synonyms: augur, call, forecast, foretell, presage, prognosticate, prophesy, read, vaticinate

[+] more

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addict, afflict, conflict, constrict, convict, debut, depict, district, edict, evict, inflict, restricked, restrict, unlicked, verdict

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Next Word in the Dictionary: predictably
Previous Word in the Dictionary: predicatory
All Words Near: predict

Seen & Heard [illegible]

What made you want to look up *predict*? Please tell us where you read or heard it (including the quote, if possible).

8 comments Add a comment

Paddy Cosgrave Teacher at ESDS CT

This whole page (in fact search) has been tiresome, interrupted and, in the end, utterly unhelpful. Shame on you, pretending to be a real dictionary!

Reply · 4 Like June 24 at 9:20pm

Dillon Buell Pape · Houston Community College System

I am sorry, but your entry does not answer the question, "What made you want to look up predict? Please tell us where you read or heard it (including the quote, if possible)." This is not a general complaints section, so your rant would probably be more effective if placed elsewhere, preferably with greater detail as to the exact nature of your dissatisfaction.

Reply · 1 · Like July 31 at 6:18pm

Paddy Cosgrave Teacher at ESDS CT

@Mr Pape: Your predictably (sic) response was sufficiently defensive to corroborate my complaint; further, if you think that was a rant, try a decent dictionary like the OED which consistently puts M-W to shame!

Reply · Like July 31 at 10:31pm

Dillon Buell Pape Houston Community College System

I am not quite sure what exactly about my response resulted in you detecting a "defensive" tone in it, but I was not trying to be defensive. I simply stated the fact that you did not answer the question to which this section is (supposed to be) devoted to answering, which is true, then making your original post irrelevant in the context of this section.

Perhaps you feel as if my response "corroborate[d]" your complaint by further contributing to your feeling that the experience of this website is "utterly unhelpful." Again, your original post was insufficiently detailed as to the exact nature of your dissatisfaction for it to be of any use whatsoever, even supposing that this was a general complaints section. Therefore, there is no way that I could have possibly been of greater help to you than I was. If you had posted a comple... See More

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vary verb \'ver-ē\

var·ied vary·ing

Definition of VARY

transitive verb

1 **a** : to make a partial change in : make different in some attribute or characteristic

b : to make differences between items in : DIVERSIFY

2 : to present under new aspects <*vary* the rhythm and harmonic treatment>

intransitive verb

1 : to exhibit or undergo change <the sky was constantly *varying*>

2 : DEVIATE, DIFFER

3 : to take on successive values <*y varies* inversely with *x*>

4 : to exhibit divergence in structural or physiological characters from the typical form

··· **vary·ing·ly** *adverb*

See vary defined for English-language learners »
See vary defined for kids »

Examples of VARY

The terrain *varies* as you climb higher.

The cost of a room at the hotel *varies* with the season.

Their services *vary* depending on the customer.

They've tried to improve their procedures, with *varying* degrees of success.

The diamonds *vary* in size.

Colors *vary* from light to dark.

I try to *vary* my diet by eating different kinds of foods.

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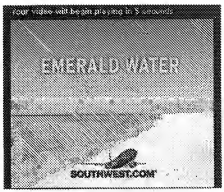

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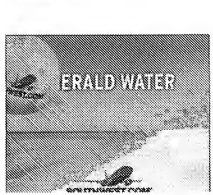

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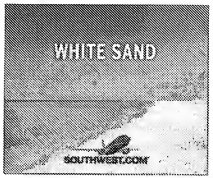

Origin of VARY

Middle English *varien*, from Anglo-French or Latin; Anglo-French *varier*, from Latin *variare*, from *varius* various

First Known Use: 14th century

Related to VARY

Synonyms: contrast, differ

Antonyms: compare, match

Thesaurus

See Synonym Discussion at change

Rhymes with VARY

aerie, airy, berry, bury, Carey, cherry, chary, dairy, Derry, faerie, fairy, ferry, Gerry, gleiry, glary, hairy, Jerry, kerry, Mary, marry, merry, nary, perry, prairie, query, scary, serry, Shari, sherry, sherry, terry, Terry, very, wary, wherry

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